

**REMARKS**

Claims 14-21, 23-26, and 28-38 are currently pending. Applicants thank the Examiner for rejoinder of claims 23-26, 29-31, and 34.

Claims 14, 23, 28-30, and 32 have been amended. None of the amendments to claims 14, 23, 28-30, and 32 constitute new matter.

The Examiner has rejected claims 32 and 33 under 35 U.S.C. § 112, first paragraph, as allegedly lacking support in the written description. The Examiner has rejected claims 14-21, 23-26, and 28-34 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner has rejected claims 14-17, 21, 23, 26, and 28-37 under 35 U.S.C. § 102(b) as allegedly anticipated by Semple *et al.*, Blood (1991) 78(10):2619-2625 (“Semple”). The Examiner has rejected claims 18-20 under 35 U.S.C. § 103(a) as being allegedly obvious over Semple. The Examiner has rejected claims 24 and 25 under 35 U.S.C. § 103(a) as being allegedly obvious over Semple in view of U.S. Patent No. 6,828,157 to Pankowsky (“Pankowsky”). For reasons detailed below, the rejections should be withdrawn and claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

**The Claims Are Properly Marked-Up**

In the Advisory Action, the Examiner notes that “some amendments, underlined, and thus, identified as being new... are already present in the claims.” Applicants note that the prior amendment erroneously underlined portions of the amended claims, and note that the claims presented herein are properly marked-up.

**Claims 32 and 33 are Definite**

The Examiner has rejected claims 32 and 33 under 35 U.S.C. § 112, first paragraph, as allegedly lacking support in the written description. The Examiner states that claims 32 and 33 lack support in the written description because the specification features additional limitations which are not recited in the present claims. The Examiner further asserts that there is no support in the specification for the terms “more than about 50%” and “less than about 20%.”

Applicants submit that the additional limitations set forth in the specification, but not recited in claims 32 and 33, are not essential or critical features of the invention, and need not be recited in the claims. Furthermore, the additional limitations cited by the Examiner are not described in the specification as being essential or critical to the claims. See, *e.g.*, MPEP § 2163(I)(B). Applicants note that the cases cited in MPEP § 2163(I)(B) all relate to applications in which an omitted element is *identified in the specification* to be an essential or critical element. *Id.* (“A claim that omits an element which *applicant describes* as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement.”) (emphasis added). In the present application, there is no indication that the additional limitations cited by the Examiner are essential or critical to claims 32 and 33 and the Examiner has provided no evidence that these limitations are essential or critical. Furthermore, the additional limitations cited by the Examiner are well known in the art, and need not be specifically recited. MPEP § 2163(II)(A)(3)(a) (“What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.”). Accordingly, claims 32 and 33 do not lack support in the written description for failing to recite limitations found in the specification.

Applicants note that claim 32 has been amended to recite “approximately 20%” instead of “less than about 20%,” and is now consistent with the language found in the specification.

See specification at page 8. With regard to the term “more than about 50%,” claim 32 has also been amended to recite “wherein ~~more than about 50% of~~ the mature human dendritic Langerhans cells have dendritic processes and more than about 50% display reactivity to anti-HLA-DR, anti-CD40, and anti-CD86 monoclonal antibodies.” Claim 32 now more particularly points out that “more than about 50%” display reactivity to various monoclonal antibodies. The specification provides support for 57.3%, 71.5%, and 98.4% reactivity with anti-HLA-DR, anti-CD40, and anti-CD86, which clearly supports this amendment. See specification at page 8. A person of ordinary skill in the art would understand that the reactivity of mature human dendritic Langerhans cells to anti-HLA-DR, anti-CD40, and anti-CD86 may vary, and therefore “about 50%” is supported by the lower level of reactivity identified in the specification, *i.e.*, 57.3% reactivity. See MPEP § 2173.05(b) (“Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.”). Accordingly, claims 32 and 33 are fully supported by the specification.

Based upon the foregoing remarks, Applicants respectfully submit that claims 32 and 33 are supported by the specification, and request that the rejection be withdrawn.

**Claims 14-21, 23-26, and 28-34 are Definite**

The Examiner has rejected claims 14-21, 23-26, and 28-37 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner states that the term “phylogenetically close species” is vague and indefinite. The Examiner has also rejected claims 24 and 34 as indefinite for lacking antecedent basis for the term “human dendritic Langerhans cells.”

Applicants note that claims 14, 28, and 37 have been amended to delete the term “phylogenetically close species.” Applicants further note that claims 23-26, 29-34 do not recite

the term “phylogenetically close species,” nor do they depend from claims that recite the term. Claims 24 and 34 have also been amended to recite “mature human dendritic Langerhans cells.” Accordingly, Applicants submit that the Examiner’s rejections have been obviated, and request that the rejection be withdrawn.

**Claims 14-17, 21, 23, 26, and 28-37 are not Anticipated**

The Examiner has rejected claims 14-17, 21, 23, 26, and 28-37 under 35 U.S.C. § 102(b), as allegedly anticipated in view of Semple *et al.*, Blood (1991) 78(10):2619-2625 (“Semple”). The Examiner asserts that Semple inherently discloses all of the limitations of the present method of producing dendritic Langerhans cells.

Applicants note that claims 14, 23, 28-30, and 32 have been amended to recite “monitoring the cultured cells for the appearance of dendritic morphology and confirming the presence of dendritic processes, wherein the presence of dendritic morphology and processes indicates the growth of mature dendritic Langerhans cells.” Support for these amendments can be found in the specification at pages 7-9. Semple does not teach this limitation; in fact, Semple makes no reference whatsoever to dendritic Langerhans cells, and is directed to the study of the secretory capacity of T-lymphocytes from patients suffering from autoimmune thrombocytopenic purpura (ATP). See Semple, page 2619, left column. Semple describes measurement of IL-2 production and <sup>3</sup>[H]-thymidine incorporation, but makes no reference to “monitoring the cultured cells for the appearance of dendritic morphology and confirming the presence of dendritic processes.” See Semple, page 2620, right column. Accordingly, Semple does not teach all of the limitations of the rejected claims, and therefore does not anticipate the present invention. Applicants respectfully request that the rejection be withdrawn.

**Claims 18-20 are not Obvious**

The Examiner has rejected claims 18-20 under 35 U.S.C. § 103(a) as obvious in view of Semple. The Examiner asserts that Semple inherently discloses all of the limitations of the present method of producing dendritic Langerhans cells, and the addition of fetal calf serum would be obvious to a person of ordinary skill in the art.

Applicants submit that the Examiner has not set forth a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner must meet three criteria. The Examiner must establish that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there is a reasonable expectation of success; and (3) the prior art reference (or references when combined) teach or suggest all the claim limitations. See MPEP §§ 706.02(j) and 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q2d 1438 (Fed. Cir. 1991).

Semple does not provide any suggestion or motivation to monitor the cultured cells for the appearance of dendritic morphology, to confirm the presence of dendritic processes, or to add fetal calf serum (FCS). As noted above, Semple is directed to the study of the secretory capacity of T-lymphocytes from patients suffering from ATP when stimulated by platelets, and only discloses monitoring cell growth and cytokine secretion by the cells. Semple does not teach or suggest that dendritic Langerhans cells may grow in these conditions, and a person of ordinary skill in the art would have no reason to monitor the cultured cells for the appearance of dendritic morphology. Furthermore, Semple makes no reference to the addition of FCS or any other

medium additive, and a person of ordinary skill in the art would have no motivation to supplement the medium used by Semple with FCS. In fact, Semple studied *relative* IL-2 secretion and cell proliferation; any medium additives which changed cell growth would, at best, simply preserve the relationship found in Semple, and at worst, change the outcome of the experiment. See Semple, page 2620-2622. Accordingly, there is no motivation in Semple to add any supplements to the medium, and therefore Semple does not provide the requisite suggestion or motivation.

A person of ordinary skill in the art would not have a reasonable expectation of success of culturing dendritic Langerhans cells based upon the disclosure of Semple. As stated above, Semple was not studying dendritic Langerhans cells, and made no reference to such cells. Based upon Semple, a person of ordinary skill in the art would not have been able to predict the development of dendritic Langerhans cells in the culture described by Semple. To show a reasonable expectation of success, “at least some degree of predictability is required.” MPEP § 2143.02. Because a person of ordinary skill in the art would not have been able to predict the formation of dendritic Langerhans cells, they therefore would not have a reasonable chance of success at culturing dendritic Langerhans cells based upon the disclosure of Semple.

As argued above, Semple does not teach or suggest the limitation of “monitoring the cultured cells for the appearance of dendritic morphology and confirming the presence of dendritic processes, wherein the presence of dendritic morphology and processes indicates the growth of mature dendritic Langerhans cells.” Furthermore, Semple makes no reference to the use of FCS, nor suggest that any additional media supplements were necessary or desirable. Accordingly, Semple does not teach or suggest all of the limitations of the claims as amended.

Based upon the foregoing remarks, Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness, and request that the rejection be withdrawn.

**Claims 24 and 25 are not Obvious**

The Examiner has rejected claims 24 and 25 under 35 U.S.C. § 103(a) as obvious over Semple in view of Pankowsky. The Examiner asserts that that it would be obvious to combine the teachings of Semple and the methods of morphological examination of cells taught by Pankowsky.

Applicants submit that the Examiner has not set forth a *prima facie* case of obviousness. Neither reference provides sufficient suggestion or motivation to combine. As discussed above, Semple does not provide any suggestion or motivation to monitor the cells for dendritic morphology, and makes no reference whatsoever to dendritic Langerhans cells. A person of ordinary skill in the art who combined Semple with Pankowsky would most likely use the method of Pankowsky to study T-lymphocytes, and therefore would not be monitoring the culture for cells with dendritic morphology. Although Pankowsky does make reference to phenotyping cells generally, Pankowsky does not provide any specific motivation to monitor the culture for dendritic Langerhans cells and confirming the presence of dendritic processes. See *In re Baird*, 16 F.3d 380, 382-383 (Fed. Cir. 1994) (stating that a generic disclosure which encompasses a specific embodiment does not support obviousness if there is no specific suggestion or motivation to choose the specific embodiment). Furthermore, it is improper to impute a suggestion or motivation to combine references simply because it is *possible* to combine the references. MPEP § 2143.01. As Semple does not teach or disclose that dendritic Langerhans cells will arise, a person of ordinary skill in the art would have no suggestion or

motivation to use the method of Pankowsky to specifically look for dendritic Langerhans cells, and would not use the method of Pankowsky to study unspecified and unknown cells which may or may not be present in the culture. Accordingly, Semple and Pankowsky do not provide the requisite suggestion or motivation to combine.

A person of ordinary skill in the art would not have a reasonable expectation of success if they did combine the references. As argued above, a person of ordinary skill in the art could not predict the growth of dendritic Langerhans cells based on the disclosure of Semple. For similar reasons, a person of ordinary skill in the art could not predict the growth of dendritic Langerhans cells based on the disclosure of Pankowsky. See MPEP 2143.02. Accordingly, Semple and Pankowsky do not present a person of ordinary skill in the art with a reasonable expectation of success.

As argued above, Semple does not teach or suggest all of the limitations of the present invention. Pankowsky is directed to a method of characterizing cells utilizing beads which bind to cell surface markers on the cells, but does not teach or suggest specifically monitoring for dendritic morphology. Neither reference mentions dendritic morphology, and do not teach or suggest the limitation of “monitoring the cultured cells for the appearance of dendritic morphology and confirming the presence of dendritic processes, wherein the presence of dendritic morphology and processes indicates the growth of mature dendritic Langerhans cells.” Accordingly, not all of the limitations of the present invention are taught by Semple and Pankowsky.

Based upon the foregoing arguments, Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness, and request that the rejection be withdrawn.




**CONCLUSION**

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. The Applicant believes that the invention described and defined by claims 14-21, 23-26, and 28-38, as amended, are patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claim is requested. An early allowance is earnestly sought.

Respectfully submitted,

BAKER BOTTS L.L.P.



Lisa B. Kole  
Patent Office Reg. No. 35,225

Van Nguyen  
Patent Office Reg. No. 56,571

Attorney for Applicants  
BAKER BOTTS L.L.P.  
30 Rockefeller Plaza  
New York, NY 10112-4498  
(212) 408-2500